

REMARKS

The Amendments

Claims 9 and 11 are amended to overcome the 35 U.S.C. §112 rejection. Claim 1 is further amended to recite that the active substance “consists of” the therapeutically effective amount of a salt of tiotropium. Thus, the method is distinguished by excluding other active substances. Support for the amendment is found throughout the specification. For example, see all of the examples and specifically described embodiments wherein the only active agent is a tiotropium salt. See also, page 2, third and fourth paragraphs, page 4, last paragraph, and page 10, first full paragraph.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Rejection under 35 U.S.C. §112, second paragraph

The rejection of claims 9 and 11 under 35 U.S.C. §112, second paragraph, is believed to be rendered moot by the amendments thereto. The definite article the is replaced where not appropriate.

The Rejection under 35 U.S.C. §102

The rejection of claims 9 and 11-32 under 35 U.S.C. §102, as being anticipated by Pairet (US Pub. No. 2002/0122773), is respectfully traversed.

It is believed that the above amendment to claim 9 clearly distinguishes the claimed invention from the Pairet disclosure. Pairet requires the combination of two active substances, i.e., an anticholinergic and a dopamine agonist; see, e.g., the Summary of the Invention (page 1, para. 0002), page 1, paras. 0007-0009, and all of the examples. Pairet, therefore, does not disclose and anticipate a method which “comprises administering, via inhalation, a formulation comprising an active substance which consists of a therapeutically effective amount of a salt of tiotropium, and, optionally, physiologically acceptable excipients.” The “consists of” language in claim 9 excludes from the claimed method embodiments wherein the salt of tiotropium is administered in combination with another active substance. Thus, it excludes the Pairet method requiring the additional dopamine agonist active substance. Accordingly, Pairet does not anticipate the claimed invention and

the rejection under 35 U.S.C. §102 should be withdrawn.

Applicants also point out that Pairet is excluded from application as prior art for obviousness purposes in view of 35 U.S.C. §103(c). Applicants hereby state that the subject matter described in Pairet and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. Thus, Pairet cannot be applied as prior art for obviousness purposes under 35 U.S.C. §102(e)/103.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

No fee, other than the 1-Month Extension of Time being paid herewith, is believed to be due with this Amendment. However, the Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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